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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/705,725

11/10/2003

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14485.0154US01

5023

23552 7590 10/16/2008
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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

10/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/705,725	Applicant(s) FAUST ET AL.	
	Examiner CHRISTOPHER D. KOHARSKI	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 12-24 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14 is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-13, and 15-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 12/24/2007 in which claims 9, 15, 17, and 22-23 were amended. Currently claims 1-9 and 12-24 are pending for examination in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Hunn et al. (US2004/0158207). Hunn et al. discloses an infusion set.

Regarding claims 1-6, Hunn et al. discloses a device (Figures 9-17) for automatically retracting a needle (8) used to introduce a cannula (1) of a subcutaneous infusion device (1) into a subcutaneous layer of skin of a patient, the device comprising: a housing (4) defining an internal cavity; a needle hub (27a) coupled to the housing and including a needle (8), the needle being coupled to a cannula (1) of a subcutaneous infusion device; a spring (22) configured to move the needle into a retracted state; and a trigger member (25) including projections (28b); wherein, upon full introduction of the needle (8) and associated cannula (1) of the subcutaneous infusion device into a

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subcutaneous layer of skin of a patient, the projections (28b) release the needle hub (27a), and the spring (22) automatically moves the needle into the internal cavity of the housing into the retracted state while leaving the cannula (1) of the subcutaneous infusion device in the subcutaneous layer of skin of the patient, further comprising a second spring (21) configured to introduce the needle (8) and associated cannula (1) of the subcutaneous infusion device into the subcutaneous layer of skin of the patient, wherein the housing includes a first portion (27) coupled to the needle, and a second portion that is slideably received in the first portion, wherein the first portion slides relative to the second portion (6) to introduce the needle into the subcutaneous layer of skin of the patient; further comprising means for covering (2) the needle prior to introduction of the needle into the subcutaneous layer of skin of the patient (Figures 1-18, cols 1-2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-9, 12-13, and 15-24 are rejected under 35 U.S.C 103(a) as being unpatentable over Hunn et al. (US2004/0158207) in view of Vetter et al. (USPN5,135,496). Hunn et al. meets the claim limitations as described above except tamper evident seal and cap.

However, Vetter et al. teaches a tamper-proof hypodermic syringe assembly.

Regarding claims 7-9, 12-13, and 15-24, Vetter et al. teaches syringe device (Figure 1) comprising a cap (7) configured to be coupled to a housing (2), the cap (7) including a tamper-evident band (9), wherein the tamper-evident band (9) remains coupled to the housing (2) when the cap (7) is removed from the housing (Figures 1-2).

At the time of the invention, it would have been obvious to add the tamper-proof cap assembly of Vetter et al. to the system of Hunn et al. in order to add additional sterility to the system and prevent re-use. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Vetter et al. (cols 1-2).

Allowable Subject Matter

Claim 14 is allowed.

Response to Arguments

Applicant's arguments filed 12/24/2007 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Hunn et al. reference does not disclose a trigger member including projections that, upon full introduction of the

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needle and associated cannula of the subcutaneous infusion device into a subcutaneous layer of skin of a patient.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the trigger (25) mechanism of Hunn et al. includes projections (28b) that upon full introduction in the skin, the patient can actuate the trigger (25) to release the projections (28b) from the hub to permit automatic retraction via the spring (22).

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 10/14/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763